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Lipovsky 12/09/85 125 807,30<u>4</u>

Nicholas S. Bodor

Before the Board of Appeals

SOFT STEROIDS HAVING ANTI-INFLAMMATORY ACTIVITY

MAILED

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Norman H. Stepno for Appellan GROUP 120

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Examiner's Answer

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APR 1000

This is an appeal from the final rejection of claims 1-45, 56-63 and 65-117. Claim 118 was deemed allowable. Claims 46-51 were objected to. No amendments after final were filed. A correct copy of the appealed claims appears on page 1-22 of appellant's brief.

The References Relied on are:

3,558,675 Sarett et al. 1/71
3,856,828 Phillipps et al. (1) 12/74
4.093,721 Phillipps et al. (2) 6/78
4,263,289 Edwards 4/81

The claimed invention is set forth on pages 24-26 of appellants brief.

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The Rejection

Claims 1-45, 56-63 and 65-117 stand rejected under 35 U.S.C. 103 as being unpatentable over Phillipps et al. (1)(2) and Edwards in combination with Sarrett et al. The primary references teach 17-alpha-hydroxy and acylyoxy substituted anti-inflammatory 17-beta-carboxylated andCrostane steroids. The Sarett patent shows the conventionality of modifying a steroidal 17-alpha hydroxy substituent with oxy-carboxyl-oxy substituents. Modification of the compounds shown by the primary references with a carbonate ester at the 17-alpha position, as recited in the claims, would be obvious to one of ordinary skill in the art with the references of record before him. Hence, the claims are precluded from patentability by the statute. The composition claims as well as the method of use claims would be equally as obvious to one of ordinary skill in the art.

REPONSE TO APPLICANTS ARGUMENTS

The nexus of the instant appeal resides in whether the teaching of Sarett et al. would be applicable to steroids in general or to only a narrow genus as appellant contends. It is the Examiner's position that Sarett et al. teach the utility of the reaction with steroids in general, with only 16 and 17 position

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substituents affecting the reaction (Note opening sentence of specification and claim 1 which treat the steroid class in a generic manner). One skilled in the steroid related art would have been motivated to combine the references herein relied upon, as discussed above, since the secondary reference of Sarett et al. relates to the utility of D ring modifications for a genus of steroids encompassing those of the primary reference. The reference of Sarett et al. further teaches that such a modification produces compounds with high activities. In an attempt to support their position alleging a narrow interpretation of the reference, appellants submitted copies of the file history of the parent applications of the Sarett patent. The examiner pointed out that claim I as originally filed in the parent applications of Sarett et al. was indeed directed to steroids in general. Appellant's quotation of the Advisory action mailed May 31, 1988 (page 29 of appeal brief) regarding this issue is incorrect. The examiner referred to appellants' allegations as "untrue" not "unique". Appellant's contention that "minor variations in the steroid molecule can provide tremendously different properties" is not reinforced by their claim language which encompasses myriad compounds (e.g. note claim 1 occupying pages 1-6 of the instantly filed brief). Modifications on the 16 and 17 positions of the steroids ring system are viewed by those skilled in the art as typically affecting the degree of activity rather than the type of activity. The Nakagawa declaration has been noted, but was not deemed in point it failed to address the expected utility of compounds produced a result of the combination of the

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cited references.

For the reasons set forth above, the rejection of claims 1-45, 56-63 and 65-117 under 35 USC 103 is seen as sound and should be maintained. Likewise, the objection to claims 46-51, caused by the aforementioned rejection should also be upheld.

Respectfully submitted,

DOUGLAS W. ROBINSGIA PRIMARY EXAMINER

ART UNIT 125

LIPOVŠKY:rbk 703/557-3920

12/12/88

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